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THOMAS G. BRUTON
CLERK, U.S. DISTRICT COURT

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

Douglas Memler, *Plaintiff*, v. Bristol-Myers Squibb Company, Otsuka Pharmaceutical Co., Ltd., and Otsuka America Pharmaceutical, Inc., *Defendants*.	**16 CV 10028** **JUDGE DURKIN** **MAGISTRATE JUDGE KIM** **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Douglas Memler, a Pro Se Plaintiff, brings this civil action against Defendants above-named for personal injuries suffered by Plaintiff Douglas Memler, and allege as follows:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Defendants' prescription drug Abilify.

2. Defendants manufacture, promote, and sell Abilify as a prescription drug that treats depression, bipolar I disorder, and schizophrenia. Abilify is

manufactured as tablets, oral solution, and injection.

3. Defendants' drug Abilify harmed Plaintiff, having caused harmful compulsive behaviors including compulsive gambling, resulting in substantial financial, mental, and physical damages.

4. Defendants knew or should have known that Abilify, when taken as prescribed and intended, causes and contributes to an increased risk of serious and dangerous side effects including, without limitation, uncontrollable compulsive behaviors such as compulsive gambling.

5. Defendants' labeling in Europe and Canada warns about the risk of "pathological gambling."

6. Defendants did not warn, advise, educate, or otherwise inform Abilify users or prescribers in the United States about the risk of compulsive gambling or other compulsive behaviors until May of 2016, when the FDA mandated it. Prior to January 2016, the US label made no mention of pathological gambling or compulsive behaviors whatsoever. In January 2016, Defendants simply added "pathological gambling" to the postmarketing experience section of the US label in January 2016.

PARTIES

7. Plaintiff is adult resident and citizens of DuPage, Illinois. Plaintiff Douglas Memler brings this action against Defendants for the personal injuries suffered as a result of ingesting the pharmaceutical drug Abilify.

8. Plaintiff Douglas Memler was prescribed and took the prescription drug

Abilify and as a result developed compulsive gambling behaviors. Plaintiff Douglas Memler began taking Abilify in or around March 2015, began compulsively gambling, and stopped compulsively gambling soon after Plaintiff had ceased taking Abilify in or around May 2016. Plaintiff Douglas Memler was prescribed and purchased Abilify in the State of Illinois. Due to Defendants conduct, as detailed herein, Plaintiff's injuries and their relationship to Abilify were not discovered until 2016.

9. By way of example, as a result of Abilify use, Plaintiff has suffered the following losses: monetary losses in excess of $100,000, loss of financial stability, and other mental, physical, and economic losses. The injurious impact of Abilify on Plaintiff's brain constitutes a physical injury.

10. As a result of Abilify use, Plaintiff Douglas Memler has suffered, and will

continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

11. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is incorporated in Delaware, with its principal executive office at 345 Park Avenue, New York, New York. Upon information and belief, Bristol-Myers owns and operates six facilities in the state of New Jersey.

12. Defendant Otsuka Pharmaceutical Co., Ltd., is a foreign Japanese company, with its principal office at 2-9, Kanda Tsukasa-machi, Chiyoda-ku, Tokyo 101-8535, Japan and has a registered agent located at 351 West Camden Street, Baltimore, Maryland per records filed with the Maryland Department of Assessments and Taxation Business Services. Abilify is a trademark of Defendant Otsuka Pharmaceutical Co., Ltd. Defendant Otsuka Pharmaceutical Co. Ltd. wholly owns Otsuka America, Inc. ("OAI"), a holding company established in the United States in or around 1989. OAI is the parent of Defendant Otsuka America Pharmaceutical, Inc. ("OAPI"), Otsuka Pharmaceutical Development & Commercialization, Inc. ("OPDC"), and Otsuka Maryland Medicinal Laboratories, Inc. ("OMML").

13. Defendant OAPI is incorporated in Delaware, with its principal place of business at 508 Carnegie Center Princeton, New Jersey. OAPI developed, distributed, and marketed Abilify with OPC.

14. At all times relevant to this Complaint, Defendant Otsuka Pharmaceutical Co. Ltd., OAI, OAPI, OPDC, and OMML (the "Otsuka entities") have operated in concert as it relates to the development, research, distribution, manufacturing, and/or marketing of Abilify. OPC has control over its subsidiaries daily affairs and operations with respect to Abilify. The Otsuka entities work in concert as a single operation known as the Otsuka Group.

15. Defendant Bristol-Myers has operated in concert with the other Defendants and jointly marketed, sold, and promoted Abilify in the United States with the Otsuka Group, through Defendant OAPI and otherwise.

16. Defendants are collectively engaged in the development, design, testing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of pharmaceutical products, including Abilify. Otsuka "discovered" Abilify in 1988, obtained approval in the United States in November 2002 and in Japan in January 2006.

17. Defendants Bristol-Myers and Otsuka are and have been engaged in the business of researching, testing, developing, manufacturing, packaging, distributing, licensing, labeling, promoting, marketing and selling, either directly or indirectly through third parties or related entities, the pharmaceutical drug Abilify, in all states and throughout the United States.

JURISDICTION

18. This Court has federal subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

19. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

20. In particular, a foreign defendant may be sued in this judicial district pursuant to 28 U.S.C. § 1391(c)(3).

21. The domestic Defendant entities are residents of, and operate in, this judicial district for purposes of venue pursuant to 28 U.S.C. §§ 1391(b)(1), (c)(2), (d).

22. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of marketing, promoting, distributing, and selling prescription drug products, including the Abilify products, within the State of Illinois, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

23. This court has personal jurisdiction over Otsuka Pharmaceutical Co., Ltd. based on its contacts with Illinois relating to the subject matter of this action and because Otsuka Pharmaceutical Co., Ltd. has continuous and systematic contacts with this judicial district. On information and belief, Otsuka

Pharmaceutical Co., Ltd. regularly places goods into the stream of commerce for distribution in Illinois and throughout the United States. Members of Otsuka Pharmaceutical Co., Ltd. continuously communicate from Japan with members of Otsuka America Pharmaceutical, Inc.

24. Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because Defendants did and do business within and have continuous and systematic contacts with the State of Illinois, have consented to jurisdiction in the State of Illinois and/or committed a tort in whole or in part in the State of Illinois against Plaintiff, as more fully set forth herein. On information and belief, Defendants also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

25. Jurisdiction is proper under 735 ILCS 5/2-209 Sec. 2-209 and the due process clause of the Constitution because Defendants have sufficient minimum contacts with the State of Illinois related to Abilify and have purposefully directed conduct toward the State of Illinois.

FACTUAL BACKGROUND

26. Abilify was first introduced to the market in the United States in or around the fall of 2002. Abilify is an atypical anti-psychotic prescription medicine

discovered by Defendant Otsuka Pharmaceutical Co., Ltd.

27. In or around October or November of 2012, the European Medicines Agency required that Defendants warn patients and the medical community in Europe that Abilify use included the risk of pathological gambling.

28. In particular, the European Medicines Agency required the European labeling for Abilify to carry the following language in the Special Warnings and Precautions For Use section of the label:

> **Pathological gambling**
>
> **Post-marketing reports of pathological gambling have been reported among patients prescribed ABILIFY, regardless of whether these patients had a prior history of gambling. Patients with a prior history of pathological gambling may be at increased risk and should be monitored carefully.**

29. The European labeling for Abilify also carries additional language concerning adverse reactions that have been reported during post-marketing surveillance relating to gambling side effects. Under a section entitled "Undesirable effects," it provides:

> **Psychiatric disorders: agitation, nervousness, pathological gambling, suicide attempt, suicidal ideation, and completed suicide.**

30. In or around November 2015 Canadian regulators concluded that there is "a link between the use of aripiprazole and a possible risk of pathological gambling or hypersexuality" and found an increased risk of pathological (uncontrollable)

gambling and hypersexuality with the use of Abilify.

31. In or about November 2015 the following warning statement for the risk of pathological gambling was added to the Canadian prescribing information for Abilify:

Pathological Gambling

> **Post-marketing reports of pathological gambling have been reported in patients treated with ABILIFY. In relation to pathological gambling, patients with a prior history of gambling disorder may be at increased risk and should be monitored carefully.**

32. Despite these warnings and advisories in Europe and Canada—for the same drug sold to patients in the United States—the labeling for Abilify in the United States did adequately warn about the risk of compulsive gambling and contained no mention that pathological gambling has been reported in patients prescribed Abilify until January 2016 when pathological gambling was added only to the Postmarketing Experience section of the label. Defendants did not make any mention of gambling in the patient medication guide, a source of information likely viewed by physicians and patients.

33. The labeling for Abilify in the United States contained no mention of the word "gambling" until January 2016.

34. In May 2016, the FDA put out an additional warning about Abilify. "FDA is warning that compulsive or uncontrollable urges to gamble, binge eat, shop, and have sex have been reported with the use of the antipsychotic drug aripiprazole (Abilify, Abilify Maintena, Aristada, and generics). These uncontrollable urges

were reported to have stopped when the medicine was discontinued or the dose was reduced. These impulse-control problems are rare, but they may result in harm to the patient and others if not recognized."

35. Defendants wrongfully and unjustly profited at the expense of patient safety and full disclosure to the medical community by failing to include language

about gambling in the United States labeling and by failing to otherwise warn the public and the medical community about Abilify's association with gambling—despite opportunities and a duty to do so. As a result, Defendants have made significantly more revenue from Abilify sales in the United States compared to Europe.

36. Defendant Bristol-Myers touts Abilify as its "2013 largest-selling product" noting sales of $2.3 billion. Defendant Bristol-Myers recently reported U.S. revenues from Abilify sales of $417 million over three months ending June 30, 2014, and worldwide revenues of $555 million over the same time period.

37. Since its introduction to the United States market, Abilify has generally been used to treat patients with schizophrenia, bipolar disorder, as an adjunct for depression, and autism spectrum disorders.

38. In 2001, Defendant Otsuka Pharmaceutical Co., Ltd., submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") for Abilify (aripiprazole). This initial NDA sought approval to market Abilify in 2, 5, 10, 15, 20 and 30 mg tablets as a treatment for schizophrenia. The NDA was approved on November, 15 2002.

39. In November 2002, the FDA required Defendants to submit results of Study 138047 to address the longer-term efficacy of Abilify in the treatment of adults with schizophrenia.

40. On December 3, 2002, Defendant Otsuka America Pharmaceutical, Inc., submitted a Supplemental New Drug Application (NDA 21-436/S-001) on the longer-term efficacy of Abilify in the treatment of schizophrenia. This application was approved on August 28, 2003.

41. In June 2003, Otsuka Maryland Research Institute submitted another Supplemental New Drug Application (NDA 21-436/S-002) for Abilify tablets as a treatment for bipolar disorder. This application was approved on September 29, 2004.

42. In May 2007, Otsuka Pharmaceutical Development & Commercialization, Inc., submitted another Supplemental New Drug Application (NDA 21-436/S-018) for Abilify tablets as an adjunctive treatment for patients with major depressive disorder. This application was approved on November 16, 2007.

43. In contrast, in Europe, Abilify is not indicated to treat depression. The European Medicines Agency declined to approve Abilify as an add-on treatment for depression because of concerns about its efficacy for that indication.

44. In or around 1999, Defendants Bristol-Myers and Otsuka entered into an agreement to co-develop and "commercialize" Abilify (hereinafter referred to as "Defendants' Marketing Agreement"). Under terms of Defendants' Marketing Agreement, Defendant Bristol-Myers was to market and promote Abilify in the

United States and the European Union, in collaboration with Defendant Otsuka Pharmaceutical Co., Ltd., and under Defendant Otsuka Pharmaceutical Co., Ltd.'s trademark.

45. Defendants' Marketing Agreement also provided that Defendants Bristol-Myers and Otsuka Pharmaceutical Co., Ltd., would collaborate to complete clinical studies for schizophrenia, and that Defendant Bristol-Myers would conduct additional studies for new dosage forms and new indications.

46. Defendant Bristol-Meyers began co-promoting Abilify with Defendant Otsuka Pharmaceutical Co., Ltd., in the United States and Puerto Rico in or around November 2002. Defendants' Marketing Agreement was extended in or around 2009.

47. Defendant Bristol-Myers' relationship with Otsuka had been due to expire in or around April 2015, just after the predicted expiration of Abilify's patent protection in the United States. According to a revised marketing agreement, Defendant Bristol-Myers purported to no longer market and promote Abilify as of January 1, 2013, but would continue to carry out its other responsibilities, including manufacturing for sale to third-party customers. Nevertheless, Defendant Bristol-Myers continued to market and promote Abilify, for example, through its website, through September 2015.

48. Defendants had, or should have had, knowledge that Abilify can cause

compulsive behaviors like gambling. Despite their significant collective resources, and signals that Abilify is associated with compulsive behaviors such as gambling, Defendants have failed to fully and adequately test or research Abilify and its association with compulsive behaviors to the detriment of Plaintiff, Abilify users, the public, the medical community, and prescribing doctors.

49. Compulsive gambling is a major psychiatric disorder. The American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM) first recognized pathological gambling as a psychiatric disorder in 1980.

50. Originally, the disorder was classified as an impulse control disorder. The current version of the DSM, the DSM-V, renamed pathological gambling as "gambling disorder." DSM-V reclassified gambling disorder under the category Substance-Related and Addictive Disorders in order to reflect evidence that gambling behaviors activate or are activated by reward systems similar to those activated by drugs of abuse, and produce some behavioral symptoms comparable to those produced by substance abuse disorders.

51. Abilify is a partial and full dopamine agonist. Dopamine is a neurotransmitter that helps control the brain's reward and pleasure centers.

52. Dopamine's role in compulsive behavior and pathological gambling is well-known. Dopaminergic reward pathways have frequently been implicated in the etiology of addictive behavior. Scientific literature has identified dopamine as

a potential cause of pathological gambling for years.

53. Abilify's dopaminergic activity at the mesolimbic circuit, especially at the nucleus accumbens, has been associated with compulsive behavior in Abilify patients.

54. Defendants' September 2011 6-Month Periodic Safety Update Report acknowledges a plausible mechanism for pathological gambling. The Report states that an article, Chau et al., *The Neural Circuitry of Reward and Its Relevance to Psychiatric Disorders*, "does suggest a possible mechanism by which drugs that act on dopamine neurons, like aripiprazole, might possibly have some effect on behavior related to reward."

55. Defendants' September 2011 6-Month Periodic Safety Update Report submitted to the European Medicines Agency acknowledged seven serious reports of pathological gambling, three in the medical literature and four spontaneous reports. The report also noted sixteen cases of pathological gambling in the BMS company safety database.

56. The Medical Assessment of the pathological gambling cases in Defendants' September 2011 6-Month Periodic Safety Update Report did not exclude Abilify as the cause of the compulsive gambling adverse events. Defendants concluded that "a causal role of aripiprazole could not be excluded" or that "aripiprazole was suggested by the temporal relationship."

57. The European Final Assessment Report of the September 2011 6-Month Periodic Safety Update Report concluded that with regard to compulsive gambling "in all of the reported cases we have a (+) temporal; (+) dechallenge and in one case a (+) rechallenge."

58. Numerous case reports have been published in the medical literature linking Abilify to compulsive behavior, including at least seventeen cases of compulsive gambling. Gaboriau et al. examined case reports of compulsive gambling and found that the probability that pathological gambling was actually due to Abilify was "possible" in sixteen of the cases and "doubtful" in only one of the cases.

59. Several case reports demonstrate what is known as a challenge, de-challenge, and re-challenge.

60. Challenge is the administration of a suspect product by any route.

61. De-challenge is the withdrawal of the suspected product from the patient's therapeutic regime. A positive de-challenge is the partial or complete disappearance of an adverse experience after withdrawal of the suspect product. For example, a positive de-challenge occurs when a patient ceases use of Abilify and pathological gambling behaviors cease.

62. Re-challenge is defined as a reintroduction of a product suspected of having caused an adverse experience following a positive de-challenge. A positive

re-challenge occurs when similar signs and symptoms reoccur upon reintroduction of the suspect product. For example, a positive re-challenge occurs when a patient reintroduces Abilify into her treatment regime and pathological gambling behavior reoccurs in a similar manner as such behaviors had existed when the patient previously used Abilify.

63. A positive de-challenge is considered evidence that a drug caused a particular effect, as is a positive re-challenge.

64. From May 1, 2009 to May 1, 2011, the FDA received thousands of serious adverse event reports concerning Abilify (n=4599), including over two-thousand serious adverse drug experiences of which 193 involved children (0-16 years old).

65. Serious adverse events are drug experiences including the outcomes of death, life-threatening events, hospitalization, disability, congenital abnormality, and other harmful medical events.

66. From 2005 to 2013, an FDA report showed that Abilify accounted for at least fifty-four reports of compulsive or impulsive behavior problems, including thirty reports of compulsive gambling, twelve reports of impulsive behavior, nine reports of hypersexuality, and three reports of compulsive shopping.

67. A disproportionality study of the FDA Adverse Event Reporting System showed a proportional reporting ratio for compulsivity of 8.6 for Abilify. A ratio

of more than three indicates a signal of an adverse event.

68. An analysis of the FDA Adverse Event Reporting System shows an escalating number of reports. Twenty-nine reports of gambling behavior were made to the FDA in 2014.

69. The 2014 FDA Adverse Event Reporting System data shows a proportional reporting ratio for compulsive gambling of 64.3 for Abilify. The same data demonstrates Abilify is unique in this regard and compulsive gambling is not a class-wide problem among anti-psychotic medications.

70. Defendants have not adequately studied Abilify. A review of all the randomized clinical trials comparing Abilify to other schizophrenia drugs concluded that the information on comparisons was of limited quality, incomplete, and problematic to apply clinically.

71. Despite evidence that Abilify causes compulsive behaviors like pathological gambling and calls from the medical community to conduct further research and warn patients about this possible effect of Abilify, Defendants have either failed to investigate or conduct any studies on the compulsive behavior side effects of Abilify or failed to make public the results of any studies or investigations that they might have done.

72. Abilify is not very efficacious. According to a rigorous study by the Cochrane Collaboration, there is limited evidence that Abilify leads to symptom

reduction when added to antidepressants and side effects are more frequent under Abilify augmentation treatment.

73. The Drug Facts Box for Abilify for major depression includes a "summary" of the combined data from the two identical six week randomized trials that were the basis for FDA drug approval for this indication. The box shows that Abilify has only a modest benefit: on average, patients on Abilify improved by 3 points more (*on a scale of 60*) than patients on placebo, and only an additional 11% of patients had a clinically important response as defined in the trial.

74. Despite the risks of serious adverse events, and the lack of adequate testing, Defendants aggressively promoted Abilify, including illegal promotion for off-label use. In 2007, Defendant Bristol-Myers reportedly paid $515 million to settle federal and state investigations into off-label marketing of Abilify for pediatric use and to treat dementia-related psychosis. Defendant Otsuka American Pharmaceutical, Inc., later paid more than $4 million to resolve the allegations.

75. The FDA issued a letter dated April 17, 2015 finding Abilify promotional material "false or misleading because it makes misleading claims and presentations about the drug." The FDA found the material "misleading because it implies that Abilify offers advantages over other currently approved treatments for bipolar disorder or MDD when this has not been demonstrated." The FDA also found the cited references "not sufficient to support claims and presentations suggesting that

Abilify has been demonstrated to modulate dopaminergic and serotonergic activity, or modulate neuronal activity in both hypoactive and hyperactive environments in humans."

76. Upon information and belief, Defendants have invested millions of dollars in teams of pharmaceutical sales representatives who visit and contact members of the medical community, including prescribing doctors, purporting to "educate" them about Abilify. Upon information and belief, these pharmaceutical sales representatives have not notified patients, the medical community, or prescribers in the United States that Abilify use causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction.

77. Defendants have invested millions of dollars in "Direct to Consumer" advertising. None of the advertising in the United States notifies patients, the medical community, or prescribers that Abilify use causes, is linked to, or might be associated with compulsive gambling, pathological gambling, or gambling addiction.

78. Defendants' Direct to Consumer advertising minimizes risks while over-promoting the drug.

79. As a result of Defendants' misleading promotional campaigns, Abilify occupies the top sales position for a prescription drug in the United States (but has

only reached seventh place in the global ranking of drug sales).

80. Defendants have made payments to doctors to promote Abilify. From August 2013 to December 2014, $10.6 million in payments relating to Abilify were made to 21,155 physicians in the United States.

81. To date, Defendants have not adequately notified or warned patients, the medical community, or prescribers in the United States that Abilify use causes, is linked to, and is associated with compulsive gambling, pathological gambling, or gambling addiction.

82. Defendants have not sent out any "Dear Doctor" letters to inform the medical community of the risk or association of Abilify use and gambling.

83. The labeling for Abilify in the United States lists serious side effects that have been reported with Abilify, but did not list gambling, pathological or otherwise in any form until January 2016 when it was only added to the postmarketing experience section of the label. The label still does not mention compulsive behaviors other than pathological gambling or adequately warn patients about the risk of compulsive gambling.

84. The labeling in the United States contradicts the labeling in Europe and Canada by not providing adequate warnings and not cautioning that patients should be closely monitored, and does not adequately inform patients and physicians that gambling and other compulsive behaviors have been associated with Abilify use.

85. Defendant Otsuka America Pharmaceutical, Inc., maintains a website promoting Abilify, www.abilify.com. The website includes, among other information, "tips for taking Abilify," links to "a 30-day free trial & savings on refills," and "important safety information" for Abilify.

86. Also, Defendant Otsuka America Pharmaceutical, Inc., operated another website promoting Abilify, www.addabilify.com. Prior to 2015, this website included, among other information, "important safety information," "tips for family and friends," "treatment FAQs," "side effects FAQs," and "what your doctor needs to know" concerning Abilify. Nowhere on the website did it mention to the word "gambling."

87. Defendant Bristol-Myers promotes Abilify on its own website, www.bms.com ("BMS website"), noting it was approved in November 2002 and is "jointly marketed in the U.S. by Bristol-Myers Squibb and Otsuka America

Pharmaceutical." The BMS website also includes a link to the www.abilify.com website. Nowhere on the BMS website does it mention the word "gambling."

88. Likewise, Defendant Otsuka Pharmaceutical Co., Ltd., promotes Abilify on its own website, www.otsuka.co.jp/en/ ("Otsuka website"), noting it was "researched and developed by Otsuka Pharmaceutical" and "launched" in the United States in 2002. Nowhere on the Otsuka website does it mention the word "gambling."

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

89. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including the discovery rule and/or fraudulent concealment.

90. The discovery rule should be applied to toll the running of the statute of limitations until the Plaintiff discovered or reasonably should have discovered Plaintiff's Douglas Memler injury and the causal connection between the injury and Defendants' product.

91. Despite reasonable and diligent investigation by Plaintiff into the causal connection between Plaintiff' injuries and Abilify, the cause and nature of Plaintiff' injuries and their relationship to Abilify was not discovered until 2016. Therefore, under the appropriate application of the discovery rule, Plaintiff' suit was filed well within the applicable statutory limitations period.

92. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the truth, quality and nature of Plaintiff's injuries and the connection between the injuries and Defendants' tortious conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff Douglas Memler and Plaintiff's prescribing physicians the true risks associated with Abilify.

93. Defendants were under a duty to disclose the true character, quality and nature of the risks associated with use of Abilify as this was non-public information over which Defendants had and continue to have exclusive control and because Defendants knew that this information was not available to Plaintiff Douglas Memler, Plaintiff's medical providers and/or to Plaintiff's health-care facilities. In addition, Defendants are estopped from relying on any statute of limitation because of their intentional concealment of these facts.

94. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

FIRST CAUSE OF ACTION
Strict Liability – Design, Manufacturing and Warning

95. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

96. Defendants had a duty to provide adequate warnings and instructions for Abilify, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test its product.

97. The Abilify manufactured and/or supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, it was in an unreasonably dangerous and a defective condition for its intended use and it posed a risk of serious compulsive behaviors and harm to Plaintiff and other consumers which could have been reduced or avoided, *inter alia*, by the adoption of a feasible reasonable alternative design.

98. The Abilify manufactured and/or supplied to Plaintiff by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, Abilify had not been adequately tested, was in an unreasonably dangerous and a defective condition, and it posed a risk of serious compulsive behaviors and harm to Plaintiff and other consumers.

99. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug.

100. The Abilify manufactured and/or supplied to Plaintiff by Defendants was defective due to inadequate warnings or instructions concerning the true risks of its use.

101. Defendants knew or should have known through testing, scientific

knowledge, advances in the field or otherwise, that the product created a risk of serious compulsive behaviors and harm, and was unreasonably dangerous to Plaintiff and other consumers, about which Defendants failed to warn.

102. The Abilify manufactured and/or supplied to Plaintiff by Defendants was defective, dangerous, and had inadequate warnings or instructions at the time it was sold, and Defendants also acquired additional knowledge and information confirming the defective and dangerous nature of Abilify. Despite this knowledge and information, Defendants failed and neglected to issue adequate warnings or post-sale warnings that Abilify causes serious compulsive behaviors and harm.

103. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Abilify, including Plaintiff and Plaintiff's physicians, and instead continued to sell Abilify in an unreasonably dangerous form without adequate warnings or instructions.

104. By failing to adequately test and research compulsive behaviors and harms associated with Abilify use, and by failing to provide appropriate warnings about Abilify use and associations with compulsive behaviors such as gambling, patients and the medical community, including prescribing doctors, were inadequately informed about the true risk-benefit profile of Abilify and were not sufficiently aware that compulsive behaviors such as gambling might be associated with Abilify use. As such, the medical community was not learned on the true

risk-benefit profile of Abilify. Nor was the medical community, patients, patients' families, or regulators appropriately informed that compulsive behaviors such as gambling might be a side effect of Abilify use and should or could be reported as an adverse event.

105. As a direct and proximate result of Defendants' conduct, including the inadequate warnings, dilution or lack of information, lack of adequate testing and research, and the defective and dangerous nature of Abilify, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

SECOND CAUSE OF ACTION
Breach of Express Warranty by Defendants

106. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

107. Defendants expressly warranted to physicians and consumers, including Plaintiff and/or Plaintiff's physicians, that Abilify was safe and/or well-tolerated.

108. Abilify does not conform to these express representations because it is not safe and/or well-tolerated because it causes compulsive behaviors such as pathological gambling addiction which in turn can lead to financial ruin, job loss, familial devastation, and suicide attempts.

109. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug.

110. As a direct and proximate result of the breach of Defendants' warranties, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

111. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

112. At the time Defendants marketed, sold, and distributed Abilify, Defendants knew of the use for which Abilify was intended and impliedly warranted Abilify to be of merchantable quality, safe and fit for such use.

113. Defendants knew, or had reason to know, that Plaintiff and Plaintiff's physicians would rely on the Defendants' judgment and skill in providing Abilify for its intended use.

114. Plaintiff and Plaintiff's physician reasonably relied upon the skill and judgment of Defendants as to whether Abilify was of merchantable quality, safe, and fit for its intended use.

115. Contrary to such implied warranty, Abilify was not of merchantable quality or safe or fit for its intended use, because the product was, and is, unreasonably dangerous, defective and unfit for the ordinary purposes for which Abilify was used.

116. Also, Abilify's limited and unproven effectiveness did not outweigh the

risks posed by the drug.

117. As a direct and proximate result of the breach of implied warranty, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

FOURTH CAUSE OF ACTION
Negligence

118. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

119. At all times material herein, Defendants had a duty to exercise reasonable care and the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning, and post-sale warning, testing, and research to assure the safety of the product when used as intended or in a way that Defendants could reasonably have anticipated, and to assure that the consuming public, including the Plaintiff and Plaintiff's physicians, obtained accurate information and adequate instructions for the safe use or non-use of Abilify.

120. Defendants had a duty to warn Plaintiff, Plaintiff's physicians, and the public in general of Abilify's dangers and serious side effects, including serious compulsive behaviors like pathological gambling addiction, since it was reasonably foreseeable that an injury could occur because of Abilify's use.

121. At all times material herein, Defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Abilify was not properly manufactured, designed, compounded, tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, and/or prepared.

122. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug.

123. Each of the following acts and omissions herein alleged was negligently and carelessly performed by Defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to:

a. Negligent and careless research and testing of Abilify;

b. Negligent and careless design or formulation of Abilify;

c. Negligent and careless failure to give adequate warnings that would attract the attention of Plaintiff, Plaintiff's physicians, and the public in general of the potentially dangerous, defective, unsafe, and deleterious propensity of Abilify and of the risks associated with its use;

d. Negligent and careless failure to provide instructions on ways to safely use Abilify to avoid injury;

e. Negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Abilify;

f. Negligent representations that Abilify was safe and/or well-tolerated; and

g. Negligent and careless failure to issue adequate post-sale warnings that Abilify causes an increased risk of compulsive behaviors, including pathological gambling.

124. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

FIFTH CAUSE OF ACTION
Negligence Per Se
(Violations of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

125. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

126. At all times herein mentioned, Defendants had an obligation to abide by the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Abilify.

127. By reason of its conduct as alleged herein, Defendants violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Abilify;

b. Defendants failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendants failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57;

d. Defendants advertised and promoted Abilify in violation of 21 C.F.R. § 202.1; and

e. Defendants violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Abilify label to reflect the evidence of an association between Abilify and the serious compulsive behaviors suffered by Plaintiff.

128. These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff.

129. Defendants' violations of these statutes and regulations constitute negligence per se.

130. As a direct and proximate result of Defendants' statutory and regulatory violations, Plaintiff, a member of the class of persons protected by the above-mentioned statutes, has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

SIXTH CAUSE OF ACTION
Negligent Misrepresentation

131. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

132. Defendants misrepresented to consumers and physicians, including Plaintiff and/or Plaintiff's physicians and the public in general, that Abilify was safe and/or well-tolerated when used as instructed, and that Abilify showed that Abilify was safe and/or well-tolerated, when, in fact, Abilify was dangerous to the well-being of patients.

133. Also, Abilify's limited and unproven effectiveness did not outweigh the risks posed by the drug.

134. At the time Defendants promoted Abilify as safe and/or well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Abilify was dangerous to the well-being of Plaintiff and others.

135. Defendants failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Abilify and

otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physicians, and the public in general.

136. Defendants made the aforesaid representations in the course of defendants' business as designers, manufacturers, and distributors of Abilify despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

137. At the time the aforesaid representations were made, Defendants intended to induce Plaintiff and/or Plaintiff's physicians to rely upon such representations.

138. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff received Abilify, Plaintiff and/or Plaintiff's physicians, and the public in general reasonably believed them to be true. In reasonable and justified reliance upon said representations by Plaintiff and/or Plaintiff's physicians, Plaintiff used Abilify.

139. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

SEVENTH CAUSE OF ACTION
Violation of Illinois
Consumer Fraud and Deceptive Business Practices Act

140. Plaintiff incorporate the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

141. By reason of the conduct as alleged herein, and by inducing Plaintiff and Plaintiff's physicians to use Abilify through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts, including but not limited to fraudulent statements, concealments and misrepresentations identified herein and above, Defendants violated the provisions of 815 ILCS 505.

142. As a direct and proximate result of Defendants' statutory violations, Plaintiff was damaged by Abilify which would not have occurred had Defendants not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices and the concealment and suppression of material facts to induce Plaintiff and Plaintiff's physicians to use this products.

143. By reason of such violations and pursuant to 815 ILCS 505/10a. Plaintiff is entitled to recover all of the monies paid for Abilify; to be compensated for the cost of the medical care arising out of the use of Abilify; and to recover any and all consequential damages recoverable under the law including, but not limited to, gambling losses, both past and future medical expenses, past

wage loss, loss of future earning capacity, past and future pain, suffering, disability, and emotional distress. Plaintiff is entitled to seek compensatory damages, attorney's fees, and other remedies as determined by the Court pursuant to 815 ILCS 505/10a.

EIGHTH CAUSE OF ACTION
Fraudulent Concealment

144. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

145. Throughout the relevant time period, Defendants knew that Abilify was defective and unreasonably unsafe for its intended purpose.

146. Defendants fraudulently concealed from or failed to disclose to or warn Plaintiff, physicians, and the medical community that Abilify was defective, unsafe, unfit for the purposes intended, and was not of merchantable quality.

147. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of Abilify because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of Abilify;

b. Defendants knowingly made false claims about the safety and quality of Abilify in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of Abilify from Plaintiff.

148. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of Abilify because the facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use the product.

149. Defendants intentionally concealed or failed to disclose the true defective nature of Abilify so that Plaintiff would request and purchase Abilify, and that his healthcare providers would dispense, prescribe, and recommend Abilify, and Plaintiff justifiably acted or relied upon, to Plaintiff's detriment, the concealed or non-disclosed facts as evidenced by their purchase and use of Abilify.

150. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's physicians from acquiring material information regarding the lack of safety and effectiveness of Abilify, and are subject to the same liability to Plaintiff for Plaintiff's pecuniary losses, as though Defendants had stated the non-existence of such material information regarding Abilify's lack of safety and effectiveness and dangers and defects, and as though Defendants had affirmatively stated the non-existence of such matters that Plaintiff was thus prevented from discovering the truth. Defendants therefore have liability for fraudulent

concealment under all applicable law, including, *inter alia*, Restatement (Second) of Torts § 550 (1977).

151. As a result of Defendants' foregoing acts and omissions, Plaintiff was or still is caused to suffer or is a greatly increased risk of serious and dangerous side effects including compulsive gambling, and other severe and personal injuries, physical pain and mental anguish, diminished enjoyment of life, any and all life complications.

152. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require healthcare and services, and has incurred financial loss, medical, health care, incidental, and related expenses.

153. As a direct and proximate result of reliance upon Defendants' misrepresentations, Plaintiff has suffered, and will continue to suffer, neuropsychiatric and physical injury, emotional distress, harm, and economic loss as alleged herein.

NINTH CAUSE OF ACTION
Punitive Damages

154. Plaintiff incorporates the factual allegations set forth in paragraphs 1 to 94 as if fully set forth herein and further alleges as follows:

155. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including

Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of Abilify. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Abilify, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Abilify, despite Defendants' knowledge and awareness of the serious side effects and risks associated with Abilify.

156. Defendants had knowledge of, and were in possession of evidence demonstrating that Abilify caused serious side effects including compulsive

gambling. Notwithstanding Defendants' knowledge of the serious side effects of Abilify, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of Abilify.

157. Although Defendants knew or recklessly disregarded the fact that Abilify cause debilitating compulsive behavior side effects including compulsive gambling, Defendants continued to market, promote, and distribute Abilify to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating Plaintiff's underlying condition.

158. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Abilify and consumers from purchasing and ingesting Abilify, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing or consuming the Abilify.

159. Defendants knew of Abilify's defective nature as set forth herein, but continued to design, manufacture, market, distribute, sell and/or promote the drug as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff in a conscious or negligent disregard of the foreseeable harm caused by Abilify.

160. The aforementioned conduct of Defendants was committed with knowing, conscious, and deliberate disregard of the rights and safety of consumers

such as Plaintiff, thereby entitling Plaintiff to punitive damages in the amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks judgment in Plaintiff's favor as follows:

1. Awarding actual damages to Plaintiff incidental to the purchase and ingestion of Abilify in an amount to be determined at trial;

2. Awarding the costs of treatment for Plaintiff's injuries caused by Abilify;

3. Awarding damages for Plaintiff's neuropsychiatric, mental, physical, and economic pain and suffering;

4. Awarding damages for Plaintiff's mental and emotional anguish;

5. Awarding pre-judgment and post-judgment interest to Plaintiff;

6. Awarding gambling losses to Plaintiff;

7. Awarding punitive damages;

8. Awarding the costs and expenses of this litigation to Plaintiff;

9. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

10. For such further relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: October 25, 2016

Respectfully submitted,

Douglas Memler

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